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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467
28008	7590	02/21/2008	EXAMINER	
DNAX RESEARCH INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			02/21/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/009,445

**Applicant(s)**

BARCLAY ET AL.

**Examiner**

CELINE X. QIAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/31/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 9-24 are pending in the application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility.

Claims 9-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to the rejection, Applicants argue that a certain and exact disclosure of the biological role of the CD200R protein and its significance in a particular disease is not required in order to fulfill the utility requirement of 101 and 112. Applicants assert that the specification

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discloses more than one specific, substantial and credible utility that satisfies the requirement of 101/112, such as the antibody that bind CD200R have significant therapeutic value in the treatment of diseases or conditions where modulation of function of myeloid lineage cells is desirable as well as in autoimmune disease, rheumatoid arthritis, and transplantation rejections (page 74, lines 28-35, page 75, lines 7-12 and lines 22-26). Applicants thus conclude that the claimed invention has substantial and specific utility.

The above arguments have been fully considered but deemed unpersuasive. The reasons for lack of patentable utility of the claimed invention were set forth in detail in the office action mailed on 2/9/07. In response to the above argument, the examiner maintains the position that the specification fail to teach a substantial and specific utility for the claimed antibody. The disclosure on page 74 and 75 of the specification is a laundry list of disorders that macrophages are involved in (ranging from stroke, neurodegeneration to autoimmune disorder such as multiple sclerosis), not disorders the polypeptide encoded by SEQ ID NO:20 is involved in. Although the rat OXRH1.2 (encoded by SEQ ID NO:2) is expressed mainly on macrophages, it does not necessary mean that this receptor is involved in all types of disorder involving macrophages. Moreover, the specification does not teach whether the polypeptide encoded by SEQ ID NO:20, a homolog of the rat OXRH1.2, has the same expression pattern as the rat protein. In fact, the specification indicates that homologs of OXRH1.2, including human and rodent protein OXRH2-4 may not be closely related functionally (see page 88, lines 25-33). As such, based solely on the disclosure the cited text on page 74 and 75, the specification does not provide sufficient teaching of a substantial and specific utility for the claimed invention. Therefore, this rejection is maintained.

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In response to the enablement rejection, Applicants argue that the specification provides reasonable enablement for the claimed antibodies and fragments thereof. Applicants further argue that MPEP requires the specification teach one of ordinary skill in the art to make and use the invention that is defined by the claims of the application, not the embodiments disclosed therein. Applicants assert that one than one use is disclosed in the instant specification as well as detailed description on how to make the claimed compositions, and nothing more is required to satisfy the enablement.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed invention were set forth in the previous office action. The 112 1<sup>st</sup> statute requires the specification to teach not only how to make, but also how to use the claimed invention according to the embodiments disclosed in the instant specification. Although any enabled use that would reasonably correlate with the entire scope of the claim is sufficient to preclude a rejection for enablement based on how to use, the specification fails to disclose such use for reasons discussed in the previous office actions. Applicants are invited to point out how to make and use the claimed invention according to the teaching of the specification. Detailed teaching on how to make the claimed composition alone is insufficient to satisfy the enablement requirement. Therefore, for reasons set forth in the previous office action and above, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Primary Examiner  
Art Unit 1636

/Celine X Qian Ph.D./  
Primary Examiner, Art Unit 1636